11-0900-11910-1

STATE OF MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS

FOR THE MINNESOTA DEPARTMENT OF HEALTH

In the Matter of the Proposed Amendments to Rules Governing Assisted Living Home Care Providers, Minnesota Rules, Chapter 4668.

REPORT OF THE ADMINISTRATIVE LAW JUDGE

The above-entitled matter came on for hearing before Administrative Law Judge Barbara L. Neilson on December 11, 1998, at 9:00 a.m. at the Minnesota Department of Health Service Center, 1645 Energy Park Drive, Saint Paul, Minnesota.

That hearing and this Report are part of a rulemaking process that must occur under the Minnesota Administrative Procedure Act[1] before an agency can adopt rules. The legislature has designed that process to ensure that state agencies—here, the Minnesota Department of Health—have met all the requirements that Minnesota law specifies for adopting rules. Those requirements include assurances that the proposed rules are necessary and reasonable and that any modifications that the Agency may have made after the proposed rules were initially published do not result in them being substantially different from what the Agency originally proposed. The rulemaking process also includes a hearing to allow the Administrative Law Judge reviewing the proposed rules to hear public comment about them.

Susan Casey, Assistant Attorney General, 525 Park Street, Suite 500, St. Paul, Minnesota 55155, appeared on behalf of the Department of Health. The Department's hearing panel consisted of Mary Absolon, Program Manager of Licensing and Certification; Linda Sutherland, Director of the Health Resource Division; Maggie Friend, Management Analyst/Rule Writer; and Mary Cahill, Senior Planner.

Approximately seventy persons attended the hearing. Thirty-nine persons signed the hearing register. The hearing continued until all interested persons, groups or associations had an opportunity to be heard concerning the adoption of these rules. Four public exhibits and ten Departmental exhibits were received into the hearing record.

After the hearing ended, the Administrative Law Judge kept the administrative record open for another twenty calendar days—that is, until December 31, 1998—to allow interested persons and the Department to submit written comments. During this initial comment period, the Administrative Law Judge received numerous written comments from interested persons and the Department. Following the initial comment period, Minnesota law[2] required that the hearing record remain open for another five

business days to allow interested parties and the Department to respond to any written comments. Several reply comments were received, and the Department proposed changes to the proposed rules. The hearing record closed for all purposes on January 8, 1999.

The Administrative Law Judge received fifty-eight written comments from interested persons during this rulemaking proceeding. The Department submitted two written comments responding to matters discussed at the hearing and in written comments and making changes in the proposed rules. Two written comments from members of the public were filed after the close of the record and could not be considered.

NOTICE

The Department must make this Report available for review by anyone who wishes to review it for at least five working days before the Department takes any further action to adopt final rules or to modify or withdraw the proposed rules. During that time, this Report must be made available to interested persons upon request.

Because the Administrative Law Judge has determined that the proposed rules are defective in certain respects, state law requires that this Report be submitted to the Chief Administrative Law Judge for his approval.[3] If the Chief Administrative Law Judge approves the adverse findings contained in this Report, he will advise the Department of actions which will correct the defects, and the Department may not adopt the rules until the Chief Administrative Law Judge determines that the defects have been corrected. However, if the Chief Administrative Law Judge identifies defects that relate to the issues of need or reasonableness, the Department may either adopt the actions suggested by the Chief Administrative Law Judge to cure the defects or, in the alternative, submit the proposed rule to the Legislative Coordinating Commission for the Commission's advice and comment. The Department may not adopt the rules until they have received and considered the advice of the Commission. However, the Department is not required to wait for the Commission's advice for more than 60 days after the Commission has received the Department's submission.

If the Department elects to adopt the actions suggested by the Chief Administrative Law Judge and makes no other changes and the Chief Administrative Law Judge determines that the defects have been corrected, then the Department may proceed to adopt the rules. If the Department makes changes in the rules other than those suggested by the Administrative Law Judge and the Chief Administrative Law Judge, then it must submit copies of the rules showing the Department's changes, the rules as initially proposed, and the Department's proposed order adopting the rules to the Chief Administrative Law Judge for a review of those changes before it may adopt the rules in final form.[4]

After adopting the final version of the rules, the Department must then submit them to the Revisor of Statutes for a review of their form. After the Revisor of Statutes approves the form of the rules, the rules must be filed with the Secretary of State. On

the day that the Department makes that filing, it must give notice to everyone who requested to be informed of that filing.

Based upon all the testimony, exhibits, and written comments, the Administrative Law Judge makes the following:

FINDINGS OF FACT

Compliance with Procedural Rulemaking Requirements

1. On April 29, 1996, the Department filed a Request for Comments on planned amendments to rules governing home care and hospice licensure. The Request for Comments was published at 20 State Register 2476.

2. A rule advisory committee was established during 1996 to provide assistance in developing revisions to the existing rule language. Meetings were held with the rule advisory committee, trade association representatives, and other interested persons.

3. On October 7, 1998, the Department filed procedural documents with the Chief Administrative Law Judge and requested that a rule hearing be scheduled and its notice plan be approved.

4. On October 14, 1998, the Department's notice plan was approved. Under that plan, notice was mailed to all currently-licensed home care providers, all establishments registered as a Housing With Services Establishment, all persons on the Department's rulemaking mailing list, and all persons or organizations on the Department's discretionary mailing list for this rule promulgation project. The Department also posted the notice on its internet website.[5]

5. On November 30, 1998, the Department mailed the Notice of Hearing to all persons and associations who had registered their names with the Department for the purpose of receiving such notice.[6]

6. The Department filed the following documents with the Administrative Law Judge at the hearing on December 11, 1998:

a) a copy of the proposed rules certified by the Revisor of Statutes (Exhibit 2);

b) the Statement of Need and Reasonableness (SONAR) (Exhibit 3);

c) the Certificate of Mailing the SONAR to the Legislative Reference Library (Exhibit 4);

d) the Dual Notice of Hearing as mailed and certificate of mailing the notice (Exhibit 5);

e) the dual Notice of Hearing as published at 23 State Register 854 on October 26, 1998 (Exhibit 6);

f) a copy of the notice provided on November 30, 1998, to those persons who requested a hearing in this matter (Exhibit 8);

g) the Certificate of Mailing the notice of hearing to those persons who requested a hearing (Exhibit 9); and

h) all public comments received by the Department regarding the proposed rules during the thirty days following the publication of the published Notice of Hearing (Exhibit 10).

7. The Department filed by mail after the hearing the Notice of Request for Comments published on April 29, 1996, at 20 State Register 2476 (Exhibit 1) and the Certificate of Mailing the Dual Notice of Hearing (Exhibit 7). These documents had been identified and received as exhibits during the December 11, 1998, hearing.

8. The Department met all of the procedural requirements established by statute and rule.

Nature of the Proposed Rules

9. In 1997, the Minnesota Legislature amended the Housing with Services Registration Act and the home care licensing laws. Further statutory changes were enacted during the 1998 legislative session. As part of these amendments, the Legislature directed that a new class of home care licensure be created entitled "assisted living home care provider." The Legislature further required that a Housing with Services Establishment that is required to obtain a home care license must obtain an assisted living home care license or a Class A or Class E license, depending upon the circumstances. The Department seeks adoption of the proposed rules involved in this proceeding in order to respond to these statutory changes as well as amendments made in 1996.

10. The existing rules set forth in Chapter 4668 of the Minnesota Rules pertain to five different classes of home care licensure. Some of the rule parts apply to all five licensure classes; others apply to only one or two of the classes. In the proposed rules, the Department seeks to reorganize and simplify the existing rules. The proposed rules add and modify definitions, amend the scope of the rules to incorporate assisted living home care providers, require licensure of providers, and establish the standards for providing services to clients. Requirements for training, recordkeeping, administration of medicines, investigation of complaints, and sanctions for noncompliance are also proposed. The Department has indicated that additional reorganization of the rules will be part of a future rulemaking project.[7]

Statutory Authority

11. In its Statement of Need and Reasonableness ("SONAR"), the Department primarily relies upon Minn. Stat. § 144A.45 as its statutory authority to adopt the proposed rules.[8] Subdivision 1 of that statute provides the Department with broad authority to promulgate rules governing the provision of home care services:

> **144A.45 Regulation of home care services.**
>
> **Subdivision 1. Rules.** The commissioner shall adopt rules for the regulation of home care providers pursuant to sections 144A.43 to 144A.48. The rules shall include the following:
>
> (a) provisions to assure, to the extent possible, the health, safety and well-being, and appropriate treatment of persons who receive home care services;
>
> (b) requirements that home care providers furnish the commissioner with specified information necessary to implement sections 144A.43 to 144A.48;
>
> (c) standards of training of home care provider personnel, which may vary according to the nature of the services provided or the health status of the consumer;
>
> (d) standards for medication management which may vary according to the nature of the services provided, the setting in which the services are provided, or the status of the consumer. Medication management includes the central storage, handling, distribution, and administration of medications;
>
> (e) standards for supervision of home care services requiring supervision by a registered nurse or other appropriate health care professional which must occur on site at least every 62 days, or more frequently if indicated by a clinical assessment, and in accordance with sections 148.171 to 148.285 and rules adopted thereunder;
>
> (f) standards for client evaluation or assessment which may vary according to the nature of the services provided or the status of the consumer;
>
> (g) requirements for the involvement of a consumer's physician, the documentation of physicians' orders, if required, and the consumer's treatment plan, and the maintenance of accurate, current clinical records;

(h) the establishment of different classes of licenses for different types of providers and different standards and requirements for different kinds of home care services; and

(i) operating procedures required to implement the home care bill of rights.

12. The phrase "home care service" is defined in Minn. Stat. § 144A.43, subd. 3, to mean nursing services, personal care services, physical therapy, speech therapy, respiratory therapy, occupational therapy, nutritional services, medical social services, and other similar medical services and health-related support services. The phrase "home care provider" is defined in Minn. Stat. § 144A.43, subd. 4, to include entities that are "regularly engaged in the delivery, directly or by contractual arrangement, of home care services for a fee."

13. The Commissioner is expressly authorized to adopt rules for the regulation of home care providers. The Administrative Law Judge concludes that the Department has the statutory authority to promulgate these rules.

Cost and Alternative Assessments in SONAR

14. Minn. Stat. § 14.131 provides that state agencies proposing rules must include in their SONAR a description of the classes of persons who probably will be affected by the rule, including those incurring costs and those reaping benefits; the probable effect upon state agencies and state revenues; whether less costly or less intrusive means exist for achieving the rule's goals; what alternatives were considered and the reasons why any such alternatives were not chosen; the costs that will be associated with complying with the rule; and differences between the proposed rules and existing federal regulations.

15. The SONAR includes a discussion of the analysis that was performed by the Department to meet the requirements of this statute.[9] With respect to the first requirement, the Department indicated that the persons who will be affected by the proposed rules are Housing with Service providers that offer one or more health-related service, the clients of such providers (and their families and friends), other home care licensees, administrators, and staff, ombudsmen, client advocates, and other interested persons. Any additional cost associated with the proposed rules is expected to be borne by home care clients and their families, the Medicaid program, and state taxpayers. The Department does not anticipate that the proposed rules will impose additional costs on licensees because many of the proposed rules revise existing rules with which such providers already must comply. In fact, the Department anticipates that existing licensees who choose to change to the assisted living home care provider license may benefit from a reduction in cost by having reduced costs due to the license fees established by statute and the flexibility of the proposed rules.[10]

16. With respect to the second requirement, the Department anticipates that it will incur additional costs in implementing the proposed rules because it is probable that there will be more home care licensees due to the promulgation of these rules. The Department will have to expend its resources and staff time to provide technical consultation concerning the proposed rules and conduct compliance checks. The Department anticipates that these additional costs will be only partially covered by license fees established by statute.[11] No other State agency is expected to incur costs.

17. The third requirement imposed by Minn. Stat. § 14.131 asks the agency to determine whether there are less costly or less intrusive methods to achieve the purposes of the proposed rules. In the SONAR, the Department stressed that the purpose of the proposed rules is to establish minimal standards for residential settings that provide health-related services and thereby assure the safety and health of all persons who receive home care services. The Department determined that these goals are more important than developing less costly or intrusive methods of regulation for assisted living home care providers. In addition, the Department indicated that many aspects of the proposed rules are based on legislative enactments during the last three years that were supported by the major provider organizations and emphasized that licensees would be free to decide what, if any, health-related services they will provide.[12]

18. The fourth provision of Minn. Stat. § 14.131 requires the agency to describe any alternative methods that were considered and the reasons they were rejected. In the SONAR, the Department identified several alternative approaches to the proposed rules, such as asking the Legislature to enact more detailed laws pertaining to home care and hospice services rather than promulgating rules. The Department rejected this alternative method of achieving the purpose of the proposed rules because the level of regulatory detail reflected in the proposed rules is best achieved by rule and not by statute. In fact, as discussed above, the governing statute directs the Department to adopt rules for the new license class and identifies some of the topics that the rules must address. The Department concluded that the level of detail in the proposed rules is necessary to ensure that clients receive adequate levels of protection. The Department also considered a second alternative method under which multiple and varied waivers to the existing rules would be allowed. Although the Department has allowed entities to request waivers from the rules in the past, the Department does not view waivers as an acceptable long-term alternative to adoption of the rules. The waiver approach makes it difficult to achieve consistent provision of services and makes it difficult for consumers to know what they can expect from a particular home care provider. The Department has determined that “it is better public policy to establish standards for a variety of levels of services to be provided, or ‘classes’ as they are called in these rules, so that providers can make clearer, better informed choices of how to be licensed based on the services to be provided, and so that consumers have more reasonable expectations of the range of services they can receive from a specific provider within a class of providers.”[13]

19. The fifth factor required to be considered under Minn. Stat. § 14.131 is the probable cost of complying with the proposed rules. The SONAR indicates that the

probable costs for licensees to comply with the proposed rules because the proposed rules retain much of the current language of the rules and waivers that have been granted. The Department further stated that new requirements set forth in the proposed rules are generally reflective of the current standards of practice in the home care industry and thus costs should be minimal. The Department acknowledged that unlicensed entities that have been providing home care services and have not been following the approaches required under the proposed rules will incur some costs to comply with the rules. The Department noted, however, that such entities should have been licensed under Minn. Stat. § 144A.43, subd. 4, and stated that the statutory changes and the proposed rules should clarify the licensure requirements. The Department also said that it was attempting to coordinate the relicensure and re-registration procedures to the extent possible.[14]

20. The sixth factor set forth in Minn. Stat. § 14.131 requires an assessment of the differences between the proposed rules and existing federal regulations. The Department indicated that some providers participate in the federal Medicare or Medicaid programs and must comply with federal standards that are significantly more stringent than the rules proposed by the Department. Because many home care providers do not provide the level of services that are required to qualify as Medicare-eligible home care services, it is not possible to rely on the existence of the federal regulatory standards to ensure the health, safety, and well-being of home care clients. The Department indicated that the differences between the proposed rules and the federal standards are the result of the differences between the types of care covered by each, and determined that it is reasonable to develop rules to address home care services that are not included in the Medicare program.[15]

21. The Administrative Law Judge concludes that the Department has met the requirement to consider alternatives to the rules as proposed.

22. A new statutory provision requires that, “wherever feasible, state agencies must develop rules and regulatory programs that emphasize superior achievement in meeting the agency’s regulatory objectives and maximum flexibility for the regulated party and the agency in meeting those goals.”[16] The Department concluded that the rules meet this standard by "providing a variety of licensing options for providers to pick and choose from, depending on their business plan and the services they choose to provide."[17] The Department also pointed out that a provider has licensure options from which to choose and can tailor its operations to serve the clients it wishes to serve.[18] The Department's approach is consistent with the legislative directive promoting superior achievement in meeting the agency’s goals and flexibility for regulated parties, where possible.

Effect on Farming Operations

23. Minn. Stat. § 14.111 (1998), imposes an additional notice requirement when rules are proposed that affect farming operations. The Administrative Law Judge finds that the proposed rules will not affect farming operations and the additional notice requirement does not apply.

Standards for Analyzing the Proposed Rules

24. In a rulemaking proceeding, the Administrative Law Judge must determine whether the agency has established the need for and reasonableness of the proposed rule by an affirmative presentation of facts.[19] An agency need not always support a rule with adjudicative or trial-type facts. It may rely on what are called “legislative facts” — that is, general facts concerning questions of law, policy, and discretion. The agency may also rely on interpretations of statutes and on stated policy preferences.[20] Here, the Department prepared a SONAR setting out a number of facts, statutory interpretations, and policy preferences to support the proposed rules. It also supplemented information in the SONAR with information presented both at the hearing and in written comments and responses placed in the record after the hearing.

25. Inquiry into whether a rule is reasonable focuses on whether the rulemaking record establishes that it has a rational basis, as opposed to being arbitrary. Minnesota law equates an unreasonable rule with an arbitrary rule.[21] Agency action is arbitrary or unreasonable when it takes place without considering surrounding facts and circumstances or disregards them.[22] On the other hand, a rule is generally considered reasonable if it is rationally related to the end the governing statute seeks to achieve.[23]

26. The Minnesota Supreme Court has defined an agency's burden in adopting rules as having to "explain on what evidence it is relying and how the evidence connects rationally with the agency's choice of action to be taken."[24] An agency is entitled to make choices between different approaches as long as its choice is rational. Generally, it is not proper for the Administrative Law Judge to determine which policy alternative might present the "best" approach, since making a judgment like that invades the policy-making discretion of the agency. Rather, the question for the Administrative Law Judge is whether the agency’s choice is one that a rational person could have made.[25]

27. In addition to ascertaining whether proposed rules are necessary and reasonable, the Administrative Law Judge must make other decisions—namely, whether the agency complied with the rule adoption procedure; whether the rule grants undue discretion to the agency; whether the agency has statutory authority to adopt the rule; whether the rule is unconstitutional or illegal; whether the rule constitutes an undue delegation of authority to another; and whether the proposed language is not a rule.[26]

28. When an agency makes changes to proposed rules after it publishes them in the State Register, the Administrative Law Judge must determine if the new language is substantially different from what the agency originally proposed.[27] The legislature has established standards for determining if the new language is substantially different.[28]

29. Numerous comments were received in writing and through testimony at the public hearing. Moreover, the Department made several modifications to the proposed rule, some of which were minor and limited in scope. This Report is generally limited to the discussion of the portions of the proposed rules that received significant critical comment or otherwise need to be examined. Persons or groups who do not find their

particular comments referenced in this Report should know that each and every suggestion has been carefully considered. The SONAR contains information establishing the need for and reasonableness of most of the proposed rules, and the Department's compliance with laws governing the rulemaking process is apparent in most cases. Furthermore, a majority of the provisions drew no unfavorable public comment. For these reasons, the Administrative Law Judge will not discuss each comment, each part or subpart of the proposed rules, or each modification made by the Department. The Judge finds that the Department has demonstrated the need for and reasonableness of all rule provisions not specifically discussed in this report. The Judge also finds that all provisions not specifically discussed are authorized by statute and that there are no other problems that would prevent their adoption.

Rule by Rule Discussion

Proposed Rule 4668.0003 – Definitions

30. Many terms used in the rules are defined in Minn. Rule part 4668.0003. In this proceeding, the definitions of some terms are amended and eight new terms are defined. Only the terms generating comments or otherwise needing discussion will be individually mentioned. The remaining definitions are found to be needed and reasonable.

31. Subpart 2a of the proposed rules defines the phrase "assistance with self-administration of mediation." The phrase is needed to describe one of the duties that may be delegated by a registered nurse to unlicensed personnel under proposed rule part 4668.0825, subp. 3. Mary Youle, Director of Housing and Community Services for the Minnesota Health & Housing Alliance (MHHA), suggested that item B, allowing "opening a container containing medications set up by a nurse" was too narrow, since pharmacists and family members also set up medications.[29] Tim Meyer and Rick E. Carter of Care Providers of Minnesota (Care Providers) suggested that the language be broadened to include other licensed professionals (such as pharmacists).[30] Noel Sorenson, R.N. Home Coordinator, Country Neighbor's Home, also commented on the requirement that medications be set up by a nurse.

32. The Department acknowledged that the item as originally written could have been interpreted to limit the ability of licensed health professionals or family members to set up medications and indicated that the provision was not intended to be limited in that fashion.[31] To conform the rule language to the intended outcome, the Department initially proposed to delete the phrase "set up by a nurse" from the item.[32] Upon further consideration, the Department decided that the rule should specify those licensed professionals who are authorized to set up medications and therefore added the phrase "set up by a nurse, physician, or pharmacist" to the rule.

33. The modification prevents potential misunderstandings as to who may appropriately set up mediations. The rules are not applicable to family members who might set up medications and therefore there is no mention of that group. The item as finally proposed for adoption has been shown to be needed and reasonable to clarify for

home care providers what is meant by the term “assistance with self-administration of medication.” The new language does not result in a rule that is substantially different from the rule as originally published in the State Register.

34. Subpart 21a defines the term "medication administration" for the purpose of assisted living services. The term is defined to include the specific tasks of checking the client's medication record, preparing the medication for administration, administering the medication to the client, documenting that the client received the medication (or that the client did not and why), and “reporting information regarding medication administration to a nurse.” Noel Sorenson suggested that the language relating to the last task be modified to require reporting to a “nurse and/or supervisor.” The Department responded that the information must be reported to a nurse since it is a delegated nursing task. MHHA complained that the last task was vague and suggested changing the language to explicitly require the reporting of information about concerns about the medication or the client’s refusal to take the medication.[33] The Department agreed with the suggestions and revised subpart 21a(E) to refer to “reporting information to a nurse regarding concerns about the medication or the client’s refusal to take the medication.” The proposed definition is needed and reasonable, as amended. The new language is not substantially different from the language originally published in the State Register.

Proposed Rule 4668.0012 - Licensure

35. Subpart 2 of Minn. R. 4668.0012 sets out the requirements for licensure when a provider has "multiple units." The proposed rules include a requirement that multiple units of a provider share the same management that supervises and administers services provided by all units. If the Commissioner of Health determines that the units cannot adequately share supervision and administration of services with the main office due to their distinct organizational structures, each unit must be separately licensed. Care Providers suggested using the term “branches” or “divisions” rather than “multiple units” to avoid confusion and more accurately describe the organizational structure of providers, and recommended that the phrase “because of distinct organizational structures” be dropped since the emphasis should be on lack of supervision and not organizational structure. The terms “multiple units” and “distinct organizational structures” were both used in the rules that previously have been adopted in this area. The proposed rule is not rendered unreasonable by its continued use of these terms in the restructured rule provision.

36. Subpart 3(A) of existing rule part 4668.0012 sets out the classes of home care licenses and specifies that providers must apply for one of these classes of licensure. The Department is adding subitem 6, the assisted living home care provider license, to that list of classes. The inclusion of this class of license is consistent with the statutory mandate of Minn. Stat. § 144A.45, subd. 1.

Proposed Rule 4668.0050 - Acceptance, Retention, and Discharge of Clients

37. Subpart 1 of the existing rules requires that all licensees have a sufficient number of qualified staff to adequately provide the agreed-upon services to the licensees' clients. The proposed rules revise subpart 1 by adding a citation to the rule part requiring service plans for clients of assisted living home care provider licensees. Care Providers supported the Department's proposed extension of this provision to assisted living home care provider licensees. Care Providers did, however, recommend that the title of the rule part be changed to include a reference to "discontinuation of services" since assisted living home care provider licensees do not "discharge" clients but instead discontinue their services.[34] The Department agreed that the additional phrase would clarify the rule and revised the title of the rule part to refer to "Acceptance, Retention, Discontinuation of Services, and Discharge of Clients." Corresponding revisions were also made in other portions of the rule. The rule as modified has been shown to be needed and reasonable to assure that assisted living home care provider licensees follow the same staffing requirement as all other licensees. The new language serves to clarify the applicability of the rule and is not substantially different from the rule as published in the State Register.

Proposed Rule 4668.0800 - Assisted Living Home Care Provider

38. This rule part describes the scope of the new assisted living home care provider license, the services such licensees may provide, the manner in which referrals to another medical or health service must be handled, and the need to have a contact person available for consultation whenever an unlicensed person employed by the licensee is performing assisted living home care services for a client. This provision also specifies that fines will be assessed for rule violations and double fines will be assessed if deficiencies are not corrected, and contains a schedule of fines for violations of subparts 3-5.

39. Subpart 2 of the proposed rules as originally proposed required that assisted living home care provider licensees must provide at least one of four listed services directly: professional nursing services, delegated nursing services, "other services performed by unlicensed personnel," or central storage of medications. Joyce M. Schowalter, Executive Director of the Minnesota Board of Nursing, suggested that adding the phrase "non-nursing" to subpart 2(c) would clarify the meaning of the "other services" that assisted living home care providers are authorized to offer clients.[35] The Department agreed that the addition of this language would clarify the rule, and accordingly modified item C to refer to "non-nursing services performed by unlicensed personnel." This modification is necessary and reasonable to explain the rule and does not constitute a substantial change from the language that was originally proposed.

40. Subpart 3 requires an assisted living home care licensee to provide all services required by the client's service plan. Kenneth C. Bittner, Administrator of the Sauer Home, Eric Hofstad, Vice President of Operations and Administration of Wesley Residence, and MHHA suggested modifying this subpart to acknowledge that the client's service plan may set forth services for which family members or other providers

may be responsible in addition to services for which the licensee is responsible. The Department responded that this option was always available and there was no need to so state in the rules.[36] The Department pointed out that the Department does not regulate services provided by non-licensed individuals such as family members, and that there is nothing in the rules that would prevent the service plan from listing the services to be provided by persons who are not affiliated with the assisted living staff.[37]

41. MHHA suggested that the use of the term "service plan" in subpart 3 of the proposed rules might imply a broader document than the term “service agreement” which is used in the current rule. The Department indicated that this issue was discussed in its Rule Advisory Committee. The Department further stated that it believes that the language of the proposed rule adequately describes what is to be included in the service plan and allows each licensee to customize the service plan for each client.[38] There is no language in the rule to suggest that a licensee becomes responsible for more tasks than those specified in each client's contract. Subpart 3 has been shown to be needed and reasonable as proposed.

42. Subpart 5 requires that assisted living home care provider licensees have a contact person who is "available for consultation" when an unlicensed person is performing assisted living home care services for a client. The Board of Nursing indicated that merely requiring a contact person was insufficient if the unlicensed person was being called to consult on delegated nursing functions. In such an instance, the Board maintained that the rule should specify that the contact person must be a registered nurse.[39] Joan Franklin, R.N., who is Community Health Services Coordinator for Sacred Heart Care Center, inc., also suggested that an R.N. be available for consultation. MHHA supported the rule language as proposed, and felt that it would allow licensees the flexibility to manage their own systems in light of the particular circumstances and the variety of available services, staffing and resources. In response, the Department noted that it agreed with the Board of Nursing but stated that the intent of the rule provision was to require licensees to have some responsible person to call at all times.[40] The Department said that the identity of that person could change with the time of day and the reason for needing to contact someone. Because the Department considers this to be a business decision, it has left it up to the provider to determine the identity of the appropriate contact person.

43. Where issues arise concerning a delegated nursing function, it is reasonable to assume that the appropriate contact person should be a licensed nurse or physician. The Department could, if it wishes, include that requirement in subpart 5. Such a revision in the language of subpart 5 would not constitute a substantial change. The language contained in the rule as proposed by the Department is not, however, rendered unreasonable by the Department’s decision to vest the provider with the discretion to determine the appropriate identity of contact persons in particular situations rather than requiring that contact persons have specific sorts of training or expertise. The general rule regarding the availability of a contact person contained in subpart 5 has been shown to be needed and reasonable.

Proposed Rule 4668.0810 - Client Records

44. Proposed rule 4668.0810 sets out the recordkeeping requirements for assisted living home care provider licensees. Subpart 5 requires that the staff person providing a service must complete documentation relating to that service by the end of the work period, and further specifies that the documentation must be entered into the client record within two weeks after the end of the day that the service was provided. Care Providers commented that the assisted living home care provider and the housing provider for a client are often separate and unrelated entities and asserted that the requirement that client records be kept on site will be difficult due to limited storage space and the need for confidentiality.[41] Care Providers further indicated that the language of the rule requires that records be maintained for clients who are not receiving services. MHHA pointed out that waivers are available for providers that lack storage space. MHHA supported the requirement that records be maintained where the services are provided. Joan Franklin, R.N., the Community Health Services Coordinator for Sacred Heart Care Center, Inc., asked whether client records were to be maintained for those in assisted living residences who do not receive home care services.

45. In its post-hearing response, the Department acknowledged that, while some assisted living home care providers and housing providers may not be the same organization, they are the same organization in the vast majority of instances. The Department indicated that the rule advisory group suggested that the client records needed to be on-site at the assisted living residence because many of the residents require unscheduled services, thereby necessitating immediate access to a client record. The rule also would permit licensees to maintain records at their business site, if that is a different location. In response to Ms. Franklin's inquiry, the Department clarified that the intent of the rule was to require recordkeeping only for those clients receiving assisted living home care provider services and indicated that it would not be necessary to maintain assisted living home care records if no such services are supplied to a client.[42]

46. Minn. Stat. § 144A.44, subd. 1(12), directs the Department to develop rules requiring the maintenance of accurate, current clinical records. The Department has demonstrated that it is reasonable and necessary to require that records be maintained at the housing with services establishment where the services are provided, in order to facilitate the transfer of information to other providers and promote continuity of care. The definition of "client" is set out in Minnesota Rule 4668.0003, subpart 5. The term is defined in that rule as "a person to whom a home care provider provides home care services." Thus, if a person is residing in licensed premises but is not receiving home care services, it is evident that the rules (including the recordkeeping requirements) do not apply. The Administrative Law Judge thus concludes that the Department has shown that subpart 5 is needed and reasonable, as proposed.

47. Subpart 6 of the proposed rule sets forth the specific information that must be included in the client record. The Board of Nursing indicated that the reference to "clinical assessment" contained in item C of subpart 6 was not meaningful since such assessments are in reality nursing assessments.[43] In its post-hearing comments, the

Department agreed to modify the rule as requested by the Board. This modification was made in response to comments received during the rulemaking process and does not result in rule language that is substantially different from the rule as originally published in the State Register.

48. As originally proposed, item F of subpart 6[44] of the proposed rules required that the client record contain "at least a weekly summary of the client's status and home care services provided." MHHA, Becky Conway, R.N., and several other commentators objected to this requirement as overly burdensome. In its post-hearing submissions, the Department indicated that the language in the proposed rule was submitted by representatives of the assisted living provider industry and represented a compromise because daily charting or charting of every encounter would be too excessive. The Department indicated that the intent of the rule was simply to have at least weekly charting of what services were provided to the client. The Department decided that, if daily charting were done, there would be no need for a weekly summary. Therefore, the Department modified the proposed rule by providing that the requirement would be triggered only where no documentation had been made of instances of self-administration of medication, medication administration, significant changes in the client's status, or significant incidents. The new language eliminates the potential for repetitive and unnecessary recordkeeping. This item, as modified, has been shown to be needed and reasonable to clarify the rule and ensure that accurate and current clinical records are maintained by licensees. The modification does not result in a rule that contains substantially different language from the rule as published in the State Register.

49. Item H of subpart 6[45] requires that the client record include "documentation on the day of occurrence of any significant change in the client's status or any significant incident, including a fall or refusal to take medications, and any actions by staff in response to the change or incident . . . ." The Board of Nursing recommended that the term "significant" be deleted from this item, in order to ensure that only licensed nursing professionals were judging the significance of changes in a client's status or an incident involving a client. The Department pointed out that the rule provision is identical to language set forth in Minn. Stat. § 144A.4605, subd. 1(d)(3), and declined to make the change sought by the Board of Nursing. It is reasonable for the Department to adopt rule language that is consistent with the language contained in the statute.

Proposed Rule 4668.0815 - Evaluation and Service Plan

50. Proposed rule part 4668.0815 sets forth various evaluation and service plan requirements that licensees must follow. Subpart 1 requires that a registered nurse complete an individualized evaluation of a client's needs within two weeks after the provider begins to provide assisted living home care services to the client and must establish a written service plan for providing assisted living home care services. MHHA supported the two-week period for completion of the evaluation and service plan and indicated that this flexibility would be helpful for out-of-town and emergency admissions and other unusual situations. MHHA urged that a trained staff person who is not a registered nurse should be permitted to perform the initial evaluation and noted that

clients needing nursing services or delegated nursing services could be referred to a registered nurse for assessment. Care Providers criticized the rule as inconsistent with other rule provisions that imply that a registered nurse must conduct a clinical assessment before the initiation of services.[46] Care Providers read this provision to mean that only registered nurses may provide services before the assessment is performed. Care Providers also suggested that the client's responsible person be permitted to sign the service plan.

51. In response, the Department explained that the purpose of the rule was to have an initial evaluation to determine what home care services may be needed and, if it is determined that nursing or delegated nursing services were needed, to require that a registered nurse conduct a clinical assessment to determine the extent and nature of those services, with a final service plan developed within two weeks. The Department indicated that licensees could ask for a variance or waiver of the rule language if they wished to obtain approval for persons other than a registered nurse to participate in the initial evaluation. The Department noted that the physician or registered nurse could choose to perform or delegate services prior to the completion of the service plan. The Department also agreed that the client's responsible person should be allowed to sign or authenticate the service plan, and revised the rule language accordingly. The Department indicated that it would consider further changes in the language of the rule recommended by MHHA and attorney Barbara Blumer in conjunction with its future revisions to Chapter 4668.[47]

52. Proposed rule part 4668.0815, as modified, has been shown to be needed and reasonable to adopt standards for client evaluation and assessment in accordance with Minn. Stat. § 144A.45, subd. 1, and protect the health and safety of clients of licensees. The modifications made by the Department to the language of this provision do not result in substantially different language from that contained in the rule as originally published in the State Register.

Proposed Rule 4668.0825 - Delegated Nursing Services

53. Proposed rule 4668.0825 applies to assisted living home care provider licensees that provide nursing services through unlicensed staff who have been delegated authority by licensed nurses. Under subpart 2 of the proposed rules, a registered nurse will be required to conduct a clinical assessment of the client's functional status and need for nursing services before nursing services are initially delegated for a client. The service plan must include the frequency of supervision of the task and of the person providing the service. The service plan for delegated nursing services will be maintained as part of the service plan discussed in connection with part 4668.0815 above. Subpart 3 of the proposed rule lists various nursing services that may be delegated to unlicensed personnel, including "performing assistance with self-administration of medication and medication administration according to part 4668.0855" and "performing routine delegated medical or nursing procedures, as provided under subpart 4." Subpart 4 of the rule specifies that persons performing delegated nursing procedures must not only satisfy the requirements of part 4668.0835, subpart 2, but also must first receive instruction by a registered nurse in the proper

methods to perform the procedures and demonstrate competency to a registered nurse. Subpart 4 also requires that a registered nurse provide written instructions for performing the procedures and imposes documentation requirements. Subpart 5 sets forth a schedule of fines for violations of each subpart.

54. Numerous providers of assisted living services participating in this proceeding have provided evidence of the importance of allowing delegated nursing services as part of the care provided to clients. Several persons, including Marie J. Janecek, Comstock Court Apartment Manager; Sandi Petersen, Executive Director of Community Services for Eventide; Kitti Solinger, Director of Adult Foster Care Services of Horizon Health; Scott Lindstrom, Program Director of Harmony House of Brainerd East; David Kern, Administrator of St. Ann's Residence; Mary B. Schreurs, B.S., R.N.C., P.H.N., Director of Home Health Services, WMMC Home Health Services; Robert B. McTaggart, Administrator and CEO of Frazee Care Center; Sharon A. Panasuk, R.N.C., Meadow Woods Assisted Living; Michael J. Demmer, President of Prairie Senior Cottages of Willmar; Judith Schuster, Director of Park View House; Sally Staggert, R.N., Franciscan Health Community; Carol A. Kappes, Director of Independent Services of Ebenezer Social Ministries; Stephen Snook, Counsel for Becklund Home Health Care, Inc.; David G. Smith, Chairman of Jasper Sunrise Village; Sue Olson, R.N., Ingleside; Marlene McGuire, R.N., L.N.H.A., Director of Client Services for Manor House; Lea Carlson, R.N.C., Senior Housing Director of Hallett Cottages; Eric D. Worke; Mick Siems, Director of The Mill Street Residence; Diane Lepp, R.N., Clinical Coordinator, Lake Region Home Health Care Services; and Wesley Residence; indicated that costs to clients were much higher when all medical administration was performed by registered nurses. Frazee Care Center indicated that the cost for unlicensed staff was $12 per hour compared to $45 per hour for registered nurses. Senior Cottages of Willmar indicated that the cost for unlilcensed staff was $9 per hour compared to at least $25 per hour for registered nurses. Franciscan Health Community indicated that, without delegation, it would see an increase in the cost of care per client of $730 per month. Wesley Residence indicated that there would be a 50% increase in staffing costs without delegation. Eric D. Worke indicated that his facility's current yearly costs for a part-time registered nurse were $8,320, and stated that that cost would increase to $174,720 if he had to hire 24-hour nursing staff. Paula K. Goblet, RN, Residence Health Coordinator of Saint Therese Residence, indicated that one to seven medication rounds are done for clients per day, seven days a week. Many individuals, including Marie J. Janecek, Comstock Court Apartment Manager, Larry C. Penk, Administrator of Pine View Apartments, Marilyn Christenson, L.S.W., Residence Director of Woven Hearts Alternative Living Services, Sandi Petersen, Executive Director of Community Services for Eventide, Linda R. O'Connor, Administrator of Karrington Cottages of Rochester, Judith Schuster, Director of Park View House, Sue Olson, R.N., of Ingleside, Russ M. Klebe, Regional Director of Housing for Ebenezer Social Ministries, Debbie Manthey, Director of Home Care and Housing for Ebenezer Social Ministries, and John Hansen, Administrator of McCarthy Manor, stressed that it is difficult to obtain the services of registered nurses, particularly outside of the major metropolitan areas in Minnesota. Care Providers commented that the rule seemed unclear in that it first implies that all nursing services may be delegated to unlicensed personnel and later identifies specific nursing services that may be so delegated, and suggested that the list

of delegated nursing services be eliminated. In addition, Care Providers objected to stringent oversight by a registered nurse.

55. Objections to the delegation of nursing functions to unlicensed personnel were raised by the Board of Nursing, the Minnesota Nurses Association, and numerous registered nurses. The Board of Nursing requested clarification of the rule to ensure that the frequency of registered nurse supervision of delegated tasks was set out in the client's plan of care.[48] The Minnesota Nurses Association urged that the rule require each licensee to "develop sound written policy and procedure that details the roles, responsibilities and reporting obligations between the administrator, RN, LPN, and unlicensed staff." The MNA expressed concern that the list of nursing services contained in the proposed rules could be misinterpreted to say that nurses cannot delegate something that is not on the list, such as monitoring of vital signs. The MNA also asserted that rules regarding nurse delegation would be more appropriately formulated by the Board of Nursing rather than the Department. The Association offered its position paper on delegation as a model of proper factors to take into consideration when deciding whether to delegate nursing functions.[49] Several persons and organizations, including Sharon Zoesch, Ombudsman for Older Minnesotans and Kerry Paarmann, R.N., Director of Patient Services for Mankato Lutheran Home Care, and the MNA, expressed concern that providers would improperly pressure nurses to delegate functions rather than allowing individual nurses to use their professional judgment to determine on a case-by-case basis whether delegation is appropriate. In addition, thirty individuals who requested that a hearing be held concerning the proposed rules expressed their view that medication administration is a complex process that should be under the direct control of trained professional registered nurses to avoid endangering vulnerable adults.

56. Eric Hofstad, Administrator, Wesley Residence, questioned the necessity of instructing unlicensed personnel with respect to each client and providing specific instructions in writing for performing routine procedures, as set forth in subpart 4, items A and B. He suggested that these requirements be eliminated or changed to agree with part 4668.0835, subp. 5.

57. In its post-hearing submissions, the Department noted that it agreed with the importance of the process used by the registered nurse to decide whether or not to delegate nursing services, as reflected in the guidelines submitted by the Minnesota Nurses Association. The Department noted that the proposed rules incorporate concepts from standards developed by organizations such as MNA and the National Council of State Boards of Nursing. The Department modified subpart 3 by adding language to clarify that unlicensed personnel who are being delegated nursing tasks must have the ability to perform nursing tasks competently. Accordingly, the Department revised subpart 3 to provide that registered nurses may delegate nursing services only to a person who satisfies the requirements of part 4668.0835 and “possesses the knowledge and skills consistent with the complexity of the nursing task being delegated, and only in accordance with Minnesota Statutes, sections 148.171 to 148.285.”[50] The Department also agreed with the Minnesota Nurses Association that licensed staff must be properly informed before delegation occurs. A new subpart

(numbered subpart 5) was proposed to require the licensee to adopt policies to assure that the registered nurse received up-to-date information as to the qualifications and training of the staff for whom delegation is sought. With respect to Mr. Hofstad's comments, the Department noted that the provisions requiring that registered nurses instruct unlicensed personnel with respect to each client and provide written instructions for performing the procedures for each client are necessary to ensure that the client's individual conditions are taken into consideration by the nurse and to promote the consistent performance of delegated tasks.

58. The Administrative Law Judge concludes that the Department has demonstrated the need for and reasonableness of its rule generally permitting registered nurses to delegate to unlicensed personnel the power to administer medications to clients or assist clients with administering medications to themselves. Minn. Stat. § 144A.4605, subd. 2, provides that home care providers may obtain assisted living licenses if, among other things, "delegated nursing services [and] other services performed by unlicensed personnel . . . are provided . . ." and "unlicensed personnel perform home health aide and home care aide tasks identified in Minnesota Rules, parts 4668.0100, subparts 1 and 2, and 4668.0110, subpart 1." The Legislature thus has implicitly authorized the performance of nursing services by unlicensed personnel to whom such services have been delegated. It is reasonable to list the specific services that a registered nurse may delegate to a person who does not have a nursing license in order to provide guidance to registered nurses, unlicensed personnel, assisted living home provider licensees, and clients. The services identified in subpart 3 of the proposed rules in fact correspond to the home health aide tasks listed in Minn. R 4668.0100, subparts 1 and 2, and the home care aide tasks identified in Minn. R 4668.0110, subpart 1, as mentioned in the statute. Subpart 3(B) of the proposed rules, which indicates that the performance of "routine delegated medical or nursing procedures" may be delegated, is sufficiently broad to encompass the monitoring of vital signs. Moreover, it is reasonable to specify the conditions under which unlicensed persons may perform these procedures because improper performance of delegated nursing services can have an adverse impact upon the health and well-being of clients served by assisted living home care providers. The Department thus has shown that part 4668.0825 is both needed and reasonable. The objections to the administration of medications made by those commenting on the rules largely focused on the specific types of medication to be administered by unlicensed personnel, the circumstances involved, and the specific means of administration. These issues will be discussed below, in conjunction with consideration of the pertinent portions of the proposed rules.

59. The modifications proposed by the Department to part 4668.0825 respond to concerns expressed by the Minnesota Nurses Association and are designed to provide guidance and information to registered nurses who are deciding the appropriateness of the delegation of nursing tasks in particular situations. The new language is not substantially different from the language contained in the rule as originally published in the State Register.

Proposed Rule 4668.0835 – Qualifications for Unlicensed Personnel who Perform Assisted Living Home Care Services

60. Proposed rule 4668.0835 identifies the qualifications needed by unlicensed personnel who provide assisted living home care services. Janice L. Carr, R.N., Director, Evergreen Place, asked whether this rule provision meant that family members of an assisted living client who perform services such as medication set-up or dressing changes had to meet the training requirements. The Department responded that it has always recognized the right of a family member to provide cares and services, and stated that such family members could provide any service they desired without having to satisfy part 4668.0835. To clarify this area further, the Department could, if it wished, amend the proposed rules to include a definition of "unlicensed personnel" which makes it clear that the term means individuals who are employed by the licensee who do not hold a nursing license and does not encompass non-employee family members or "significant others" of the client. Although the Department is not required to include such a definition, it would serve to clarify the scope of the proposed rules, would be responsive to comments and inquiries made during the rulemaking proceeding, and would not constitute a substantial change.

Proposed Rule 4668.0840 - Training and Competency Evaluation for Unlicensed Personnel

61. Proposed rule part 4668.0840 sets out detailed training and competency evaluation requirements for licensees who use unlicensed personnel to provide assisted living home care services. The proposed rule requires in subpart 2, item A, that a registered nurse "with experience or training in the subject being taught" provide training concerning each assisted living home care service offered to clients that the unlicensed person will perform. The proposed rule also requires in subpart 3, item B, that the following core training topics be taught by a registered nurse "with experience or training in home care": "observing, reporting, and documenting client status and the care or services provided;" "basic infection control;" and "basic elements of body functioning and changes in body function that must be reported to an appropriate health care professional."[51] Mary Youle of MHHA requested that the language in subpart 3(B) be revised to incorporate language similar to that in subpart 2(A). Several other individuals, including Cindy Downing, Housing Manager, and Noel Sorenson, R.N. Home Coordinator, Country Neighbor's Home, suggested that a registered nurse did not need experience or training in home care. In response, the Department indicated that the proposed language is based on Minn. Stat. § 144A.4605, which in turn references current home care rule language, and pointed out that the language of the proposed rules must be consistent with existing laws and rules. The Department also indicated that members of the Rule Advisory Committee felt that it was important that the R.N. have experience in home care because the fact that the task is being performed in a different setting is important.

62. As originally proposed, subpart 5 of part 4668.0840 required the licensee to provide each person who successfully completes the training or passes the competency evaluation with written certification that they satisfied the requirements. The Board of

Nursing commented that the term "verification" would be more appropriate than the term "certification," since the latter term is used to designate a specific type of credentialing.[52] The Department agreed with the suggestion and revised the language of subpart 5 accordingly.

63. The Department has shown that part 4668.0840 is needed and reasonable, as amended. The new language incorporated in subpart 5 is not substantially different from the rule as originally published in the State Register.

Proposed Rule 4668.0855 - Medication Administration and Assistance with Self-administration of Medication

64. The Department has proposed rule part 4668.0855 to establish a basic framework for assisted living home care provider licensees to administer medication or assist with self-administration of medication. Subpart 2 requires that a registered nurse conduct a clinical assessment of each client's functional status and need for assistance with medication and develop a service plan for the provision of services that addresses the frequency of supervision of the task and of the person providing the service. As originally proposed, subparts 3 and 4 of the proposed rule provided that registered nurses may delegate medication administration or assistance with self-administration of medication only to persons who have the qualifications required by rule part 4668.0835, subp. 2, and who have been properly trained by a registered nurse. Subpart 5 of the rules as initially proposed provided that persons who met the requirements of the rule and had been delegated the responsibility by a registered nurse "may administer medications, whether oral, suppository, eye drops, ear drops, inhalant, topical, injectable, or administered through a gastrostomy tube if . . . the medications are regularly scheduled; and . . .in the case of pro re nata medications, the administration of the medication is reported to a registered nurse either . . .within 24 hours after its administration; or . . . within a time period that is specified by a registered nurse prior to the administration." The list of tasks that could be delegated to unlicensed staff under the rules as originally proposed thus included administering medication by injection and administering pro re nata[53] (PRN) medications. The rule specifically prohibits persons to whom nursing services have been delegated from drawing up injectables. The rule part also contains provisions requiring that registered nurses instruct the unlicensed person concerning the proper methods to apply and provide written instructions for performing the procedures for each client, and sets forth documentation requirements and a schedule of fines for violations of the rule.

65. The ability of registered nurses to delegate medications to unlicensed personnel, and particularly the ability to delegate injectable medications, was a subject of controversy during this rulemaking proceeding. As noted above, thirty individuals requested a hearing on these proposed rules based upon their view that the administration of medication is a complex task that should be under the direct control of registered nurses. The Minnesota Board of Nursing also objected to part 4668.0855 insofar as the administration of medicine through injection may be delegated under the rule.[54] The Board stated:

> The department's proposal to allow unlicensed personnel to administer medication by injection directly interferes with the Board's legal authority and does not provide adequate effective assurance for the health and safety of clients. Specifically, the required training described in Part 4668.0855 subpart 4 lacks any standardization, does not require education on infection control concepts necessary for administration of medications by injection and allows all forms of injection, including intravenous, intrathecal and interarterial forms that are high risks for infection and physiological reactions by the patient.[55]

The Minnesota Nurses Association raised concerns about the delegation of administration of PRN medications to unlicensed staff. MNA asserted that the fact that two persons had died due to codeine overdoses demonstrates the need for the expertise of licensed staff when such medications are to be provided. The Association was particularly concerned about the inclusion of injectable medications in the rule and indicated that unlicensed personnel could not be taught to administer these safely. While the MNA acknowledged that there may be rare circumstances where an unlicensed person could inject, such as an anaphylactic bee sting kit or insulin for "a stable diabetic with a good ability to self-monitor blood glucose and insulin," the MNA pointed out that the Nurse Practice Act already allows R.N.s to delegate in these circumstances. The MNA expressed concern that injectables would be dangerous in the hands of unlicensed staff, given their level of concentration and their fast rate of absorption. In addition, MNA contended that the proposed language creates an expectation that R.N.s should delegate medication administration to unlicensed personnel, and urged the Department to require that unlicensed personnel attend basic training classes in medication administration.[56]

66. Rosemary O. Esler, Carol Rosenthal, R.N., Maria Cofrancesco, Pat Henton, Jodi Most, R.N., Beth Bourne, R.N., Director of Nursing at Luther Haven, Stephen J. Trost, R.N., Assistant Director of Nursing, Ramsey Nursing Home, Joan Franklin, R.N., Community Health Services Coordinator, Sacred Heart Home Health Care, Lucie Ferrell, Professor of Nursing and Health Care Ethics, Sharon Zoesch, Ombudsman for Older Minnesotans, and Iris Freeman, Executive Director, Advocacy Center for Long Term Care, were among the individuals who opposed allowing a registered nurse to delegate the administration of injectable medications to unlicensed persons. They stressed the potential risk of harm to the residents, the liability of the registered nurse, the failure of the proposed rules to require mandatory training for unlicensed personnel, and the discomfort some unlicensed personnel may have in administering medications. Several persons, including Sharon Zoesch, Ombudsman for Older Minnesotans and Kerry Paarmann, R.N., Director of Patient Services for Mankato Lutheran Home Care, expressed concern that a registered nurse's authority to limit delegation would be undermined by employers who, in an attempt to reduce costs, could replace a nurse who is unwilling to delegate tasks with one who is willing to delegate. Care Providers suggested that the rule be changed to permit only the delegation of injectable medications that are typically self-administered. Rhoda Becklund, Administrator of Becklund Home Health Care, also suggested that the rule be limited to subcutaneous or intramuscular injections or specifically limited to a treatment such as insulin.

67. Other commentators supported an approach allowing registered nurses to delegate injectable medications. These individuals included Kenneth C. Bittner, Administrator, Sauer Home; Dean R. Boemke, Managing Officer, Welcome to our Home; Normal Treptow, Manager, The Shepherd's Inn; Sally Staggert, R.N.; Jim McGowan of the American Diabetes Association; Becky Conway, R.N.; Mary Youle, Director of Housing and Community Services, Minnesota Health & Housing Alliance; Rick Buechner, Vice President of Long Term Care Services, Regina Medical Center; Debra Reinhart, R.N., Brian Fredrickson, President of Brian's Elder Care, Inc., and Suzie Spain, Caley House Assisted Living. They emphasized the cost of having a licensed nurse on site; the desirability of allowing clients to remain in assisted living settings rather than making them move to nursing homes simply due to their need for daily injections of medication; the shortage of nurses; and the need for flexibility to permit nurses to delegate injections in appropriate circumstances. MHHA emphasized that the proposed rule did not require delegation and expressly required compliance with the Nurse Practice Act when any nursing function was delegated. MHHA pointed out that delegation is frequently occurring under Class A licenses in the current home care rules.

68. Several individuals, including Eric Hofstad, Administrator, Wesley Residence, Sue Olson, R.N., Ingleside, Glenda Clifford, Lakeview Methodist Health Care Center, and Shavell Evenson, R.N., Director of Nursing Homecare, Heritage of Edina, suggested that the rules allow only the delegation of insulin. Mr. Hofstad indicated that Wesley Residence received a waiver from the Department to delegate insulin injections to unlicensed personnel. The waiver was sought in order to allow the client to remain out of a nursing home. No problems were identified as resulting from this waiver. Pamela Schwartzbauer, R.N., Director of Home Care of Crest View Corporation, indicated that the residents are in need of affordable care that could include the administration of insulin by injection. Pamela Baron Habberstad, Nelson Gables Administrator, related that her facility currently declines to accept insulin-dependent clients because a nurse is not present 24 hours a day.

69. In response to the comments received, the Department pointed out that registered nurses "have successfully delegated the administration of medications for years, and it is a very cost effective mechanism of providing services and care to clients/residents."[57] The Department emphasized that there has been "sufficient testimony on and sufficient community practice of successful delegation of medication administration that it is reasonable to continue in this legal arrangement by having the RN oversee the administration of medications in assisted living settings."[58] The Department also related that positive experience has been obtained through waivers granted to some home care providers. The Department stated:

> To date, the administration of injectables by delegation has been prohibited in existing home care rules. However, MDH has had some experience with waivers and there have been some successes with delegation of this function. It is not expressly prohibited in the Nurse Practice Act, but community standards seem slow to embrace delegation. Moreover, MDH is aware that under the Adult Foster Care regulations

> insulin is being administered by unlicensed personnel. Any Housing with Services setting which also holds a corporate adult foster care license must obtain a home care license when these rules are promulgated. Therefore, this rule is attempting to make provisions for settings we already know practice this delegation of tasks, and have been to the Dept's knowledge, successful. The proposed rule clearly makes the delegation of injectables an option, and it is the RN's professional judgement, which is used in making the decision to delegate or not to delegate.[59]

The Department also stated that the two deaths cited by the Minnesota Nurses Association occurred in Adult Foster Care settings which are licensed by the Department of Human Services, and pointed out that there is currently no requirement that registered nurses provide oversight in such settings. In contrast, registered nurse oversight is required in assisted living home care provider settings and there are proposed rules on the reporting of PRN medications to the RN.[60]

70. The Department modified the language of subpart 2 to specify that, "[for each client who will be provided with assistance with self-administration of medication or medication administration, a registered must conduct a nursing assessment . . . ." This revision was made in response to suggestions by MHHA and the Board of Nursing and serves to clarify the rule. This modification does not result in a substantially different rule from the rule as originally proposed.

71. In response to the concerns expressed by several commentators concerning the expertise of unlicensed staff, the Department also proposed in its post-hearing submission to add language to part subpart 3 expressly requiring that the person receiving the delegation possess "the knowledge and skills consistent with the complexity of medication administration or assistance with self-administration of medication . . . ."[61] This modification is a logical outgrowth of the comments submitted in response to the proposed rules and does not result in a substantially different rule from the rule as originally proposed.

72. In addition, the Department revised subpart 4 to make it clear that the training for assistance with self-administration of medication or training for medication administration must be completed prior to the time that the registered nurse delegates that activity. This modification responds to concerns expressed by the Board of Nursing regarding training and does not result in a substantially different rule from the rule as originally proposed. The Department declined to mandate a specific training program, as suggested by some commentators. The Department indicated in its post-hearing submissions that the authorizing statute places reliance on the professional judgment of the registered nurse to instruct unlicensed personnel on the tasks being delegated rather than prescribing formalized training. It is reasonable for the Department to adopt the same approach in the proposed rules. The Department indicated that it will work with the Board of Nursing, the Minnesota Nurses Association, the Board of Pharmacy, the Minnesota Home Care Association, and other interested persons to develop materials and resources for licensees to use in training their staff on these topics.

73. In its last post-hearing submission, the Department decided that it was appropriate to limit the delegation of the administration of injectable medications solely to insulin. Many of the written and oral comments specifically supported the ability of a registered nurse to delegate the injection of insulin for persons with diabetes who are unable to self-administer that medication. The Department determined that the comments submitted from industry representatives overwhelmingly identified insulin as the only medication that they would be interested in allowing unlicensed personnel to inject at this time. The Department decided that, based upon the comments submitted, there did not appear to be a compelling reason to allow the delegation of any kind of injectable medication other than insulin. A licensee could, however, request a waiver or variance from these rules if the licensee and its registered nurse wish to delegate other types of injectable medications. In reaching its determination to revise the proposed rule, the Department emphasized that most of the comments addressed the injection of insulin, the Department has a history of granting waiver requests that allow the delegation of insulin injections, there is a long history of physicians and nurses training individuals with diabetes and their family members to administer needed insulin injections, and such injections are part of the daily requirements of a person with diabetes. The Department determined that the revision reflects its attempt to balance the competing interests of clients in safety and in the availability of less-restrictive, cost-effective housing. Accordingly, the Department proposed to revise the language of subpart 5 "to clarify that the only injectable that a registered nurse could delegate under this rule part is insulin."[62] The Department cautioned that "delegation of injectables to an unlicensed person is not appropriate in every situation, depending on the client, the client's condition, the medication, possible side effects of the medication, the availability of staff to do supervision and to provide services, and the knowledge and skill of the unlicensed person that would be administering the medication."[63] Instead, the registered nurse is responsible for determining in each specific situation whether it would be appropriate to delegate the administration of insulin.

74. To accomplish the limitation, the Department modified subpart 5 to state:

> Subp. 5. **Administration of medications**. A person who satisfies the requirements of subpart 4 and has been delegated the responsibility by a registered nurse, may administer medications, ~~whether~~ including oral, suppository, eye drops, ear drops, inhalant, topical, injectable insulin, or medication administered through a gastrostomy tube, if:
>
> A. the medications are regularly scheduled;
> B. in the case of pro re nata medications, the administration of the medication is reported to a registered nurse either:
> (1) within 24 hours after its administration; or
> (2) within a time period that is specified by a registered nurse prior to the administration.

75. Using the word "including" in the context of the subpart does not limit the types of medications that may be delegated by a registered nurse. Rather, the term could be construed to allow nurses to delegate the administration of <u>any</u> medication by

any means of delivery. The language proposed by the Department does not accomplish its stated goal and this is a defect in the proposed rule.

76. To cure the defect in the proposed subpart, its language must be changed to impose limitations that are consistent with those intended by the Department and supported by the record in this proceeding. The Administrative Law Judge suggests that the Department consider adopting the following or similar language:

> Subp. 5. **Administration of medications**. A person who satisfies the requirements of subpart 4 and has been delegated the responsibility by a registered nurse, may administer medications, orally, by suppository, through eye drops, through ear drops, by use of an inhalant, topically, by injection, or through a gastrostomy tube, if:
>
> A. the medications are regularly scheduled;
> B. in the case of pro re nata medications, the administration of the medication is reported to a registered nurse either:
> (1) within 24 hours after its administration; or
> (2) within a time period that is specified by a registered nurse prior to the administration.
>
> Provided, however, that, if the medication is administered by injection, the medication is limited to insulin.

The additional proviso expressly restricts the medication to be injected by unlicensed personnel to insulin. The suggested language meets the concerns of commentators and accomplishes the outcome sought by the Department.

77. The Department has demonstrated that certain tasks, including administering insulin through injection and other medications by other means, appropriately may be delegated to unlicensed staff. While it is possible that employers could pressure nurses to improperly delegate, the rule ensures that the nurse must exercise professional judgment to decide in each instance whether delegation is appropriate. The approach taken in the rule is consistent with the statutory scheme. Because neither the Nurse Practice Act[64] nor the rules adopted by the Board of Nursing[65] impose specific limitations on what functions may be delegated by licensed nurses to unlicensed staff, the Department's proposed rules do not conflict with the Nurse Practice Act or rules. The proposed rules also do not interfere with the jurisdiction of the Board of Nursing. The Department's approach is consistent with its statutory obligation to assure the "health, safety and well-being, and appropriate treatment of persons who receive home care services."[66]

78. Proposed rule part 4668.0855, as modified by the Department and with the amendment suggested by the Administrative Law Judge, has been shown to be needed and reasonable. The changes to the rule are within the scope of the matter announced in the notice of hearing and are a logical outgrowth of the comments submitted in response to the notice, and do not result in a rule which is substantially different from the rule as originally published.

Proposed Rule 4668.0865 - Central Storage of Medication

79. This portion of the proposed rules applies to assisted living home care provider licensees who choose to provide central storage of medications. Subpart 2 requires that a registered nurse conduct an assessment of the client to determine whether central medication storage is needed and develop a service plan for the provision of that service to meet the client's needs and preferences. As originally proposed, subpart 3 provided that a registered nurse must establish and maintain a system that addresses the control, handling, and disposition of medications and the keeping of records, and sets forth particular provisions that must be included in the system. Subparts 4 through 9 discuss the treatment of over-the counter drugs, legend drugs, Schedule II drugs and medication samples, and list the schedule of fines for violation of the rule. The rules includes a requirement that drugs be stored in locked compartments under proper temperature controls and that only authorized nursing personnel have access to the keys.

80. A number of providers urged that the central storage provisions be retained in the proposed rules. For example, Scott Lindstrom, Program Director of Harmony House of Brainerd East; Kitti Solinger, Director of Adult Foster Care Services of Harmony House West of Brainerd; Beverly Heise, R.N., Director of Assisted Living Services, Martin Luther Manor; Sharon A. Panasuk, RNC, Meadow Woods Assisted Living; Virginia M. Oolman, RN, Jasper Sunrise Village; Linda R. O'Connor, Administrator of Karrington Cottages of Rochester; Sally Staggert, R.N., Franciscan Health Community; Jon Riewer, Administrator of Cokato Charitable Trust, and Pamela Schwartzbauer, R.N., Glenda Clifford of Lakeview Methodist Health Care Center, Anita Kottsick, Housing Assistant for Crest View Corporation, and Kathy Lane, Housing Administrator of Crest View Corporation, supported central storage as properly included among assisted living home care services. A large number of providers gave detailed descriptions of the procedures they use to distribute centrally stored medications to clients. David Kern, the Administrator of St. Ann's Residence, described in great detail the manner in which central storage and administration and medications are currently being performed for residents at his facility. Kitti Solinger, Director of Adult Foster Care Services of Horizon Health; Karen Finck, R.N., Bonnie Peplinski, R.N., and Becky Moore, R.N., of Health Counseling Services; Beverly Heise, R.N., Director of Assisted Living Services of Martin Luthor Manor; Sue Olson, R.N., Ingleside; Marylin Schmidt, Assisted Living Coordinator, Parkwood Apartments; John Hansen, Administrator of McCarthy Manor; and Brenda Reusch, R.N., Menahga Home Health, each provided similar descriptions of existing method of central administration of medications. Robert B. McTaggart, Administrator and CEO of Frazee Care Center noted that unlicensed staff was allowed to distribute medications in nursing homes, but not in the assisted living settings, despite the more stringent standards in assisted living. Michael J. Demmer, President of Prairie Senior Cottages of Willmar; Judith Schuster, Director of Park View House; Lea Carlson, RNC, Senior Housing Director of Hallett Cottages; Kelli Forsman, R.N.C. of Greenview Residence; Tim Samuelson, Corporate Administrator, St. John's Lutheran Home; and Becky Plocker, R.N., P.H.N., St. Luke’s Lutheran Care Center; all supported central storage of medications.

81. In contrast, the Minnesota Nurses Association expressed a concern that the provision of central storage of medication would cause the licensee to interfere in the client's self-administration of medication, thereby making the client dependent upon the provider.[67] The Association also challenged the ability of R.N.s to adequately supervise unlicensed staff when central storage of medicines is performed, and objected to allowing unlicensed staff to dispose of medications due to concern about drug dependency. It urged that the rules require at least daily supervision by R.N.s. In addition, Rhoda Becklund, Administrator of Becklund Home Health Care, Inc., objected to the potential for imposition of institutional standards on home health care. M. Catherine Griffin objected to central storage of medication in non-institutional settings. Mick Siems, Director of The Mill Street Residence, and Diane Lepp, R.N., Clinical Coordinator for Lake Region Home Health Care Services, recommended that facilities be permitted to use locked cupboards in each person's apartment in order to reduce the possibility of error.

82. Given the potential for harm arising from confusion on the part of clients and the benefit obtained from centralized control of medications, the Administrative Law Judge concludes that the necessity and reasonableness of rule provisions governing the central storage of medications by facilities that choose to provide such storage has been demonstrated.

83. In its comment, MHHA expressed concern that the language of subpart 2 could require nursing assessments of all clients if any client was receiving the central storage service.[68] MHHA suggested that the rule language explicitly limit the requirement of a nursing assessment under this rule part to those clients for whom medication is centrally stored. The Board of Nursing suggested that the rule refer to a "nursing assessment and plan of care." The Department agreed that subpart 2 of the rule should be clarified, and revised the first sentence of the rule to require that a registered nurse conduct a "nursing assessment" for a client for whom medications will be centrally stored. This modification does not result in a rule that is substantially different than the rule as originally proposed.

84. The Board of Nursing suggested that subpart 3 explicitly require that registered nurses comply with Board of Pharmacy guidelines in establishing and maintaining the medication control system.[69] The Board asserted that determining the provisions for handling drugs is a function of pharmacists and is not within the scope of practice of a nurse. The Department pointed out that the governing statute requires that registered nurses set up the medication control system,[70] possibly because assisted living home care provider licensees must have registered nurses involved in the care of its clients and are unlikely to have a pharmacist involved. Rather than requiring the registered nurse to comply with pharmacy guidelines, the Department indicated that it would work with the Board of Nursing and the Board of Pharmacy to develop training materials and resources for licensees and clients. The Department did modify the rule to allow a nurse or pharmacist to establish and maintain the system of controlling medications. The Department has demonstrated that proposed rule 4668.0865, as amended, is needed and reasonable to achieve compliance with the governing statute and impose standards to ensure that medications are handled in an appropriate and

safe fashion. The new language does not result in a rule substantially different from the rule as originally proposed.

Use of Restraints

85. Sharon Zoesch of the Office of the Ombudsman for Older Minnesotans questioned whether the proposed rules should be silent on the issue of restraint usage. Ms. Zoesch suggested that the rules include an express prohibition against the use of restraints or chemicals use due to the associated health risks. The Department pointed out that, under Minn. Stat. § 144D.07, residents must be free from restraints imposed for discipline or convenience.[71] Thus, the law already limits the use of restraints. The Department noted that the proposed change "would likely meet the threshold of a 'significant change' and could alter the progress of the rule promulgation,"[72] but stated that it would consider this recommendation as it proceeds with the revision of the entire home care rule.

86. Under the Minnesota Administrative Procedure Act, an agency may not adopt a rule if it makes changes to the rule that render the rule "substantially different" from the original version of the proposed rule that was set forth in the notice of intent to adopt rules or notice of hearing.[73] A modification does not make a proposed rule substantially different if the differences are within the scope of the matter announced in the notice of hearing and are in character with the issues raised in that notice; the differences are a logical outgrowth of the contents of the notice of hearing and the responsive comments; and the notice of hearing provided fair warning that the outcome of the rulemaking process could be the rule in question. In considering whether the notice of hearing provided fair warning, the following factors must be considered:

> (1) the extent to which persons who will be affected by the rule should have understood that the rulemaking proceeding on which it is based could affect their interests;
>
> (2) the extent to which the subject matter of the rule or issues determined by the rule are different from the subject matter or issues contained in the notice of intent to adopt or notice of hearing; and
>
> (3) the extent to which the effects of the rule differ from the effects of the proposed rule contained in the notice of intent to adopt or notice of hearing. [74]

87. The proposed rules do not address the issue of the use of restraints, and the issue was not discussed by the Department until it was raised by the commentator. The use of restraints pertains to a different subject area than is addressed by the proposed rules. No group potentially affected by the suggested prohibition would have understood that this area would be affected by the proposed rules. The record in this matter does not reflect what effect the suggested rule change would have on clients or providers, and there are no facts in the record upon which the suggested change could be based.. Based on this analysis, the Judge concludes that

the suggested modification would render the rule substantially different from the rule as originally proposed and cannot be adopted as part of this rulemaking proceeding.

Based upon the foregoing Findings of Fact, the Administrative Law Judge makes the following:

CONCLUSIONS

1. The Minnesota Department of Health ("Department") gave proper notice of this rulemaking hearing.

2. The Department has substantially fulfilled the procedural requirements of Minn. Stat. §§ 14.14, subds. 1, 1a and 14.14, subd. 2, and all other procedural requirements of law or rule so as to allow it to adopt the proposed rules.

3. The Department has demonstrated its statutory authority to adopt the proposed rules, and has fulfilled all other substantive requirements of law or rule within the meaning of Minn. Stat. §§ 14.05, subd. 1, 14.15, subd. 3 and 14.50 (i) and (ii).

4. The Department has demonstrated the need for and reasonableness of the proposed rules by an affirmative presentation of facts in the record within the meaning of Minn. Stat. §§ 14.14, subd. 2 and 14.50 (iii), except as noted at Finding No. 75.

5. The additions and amendments to the proposed rules which were suggested by the Department after publication of the proposed rules in the State Register do not result in rules which are substantially different from the proposed rules as published in the State Register within the meaning of Minn. Stat. § 14.15, subd. 3, and Minn. Rule 1400.1000, subp. 1 and 1400.1100.

6. The Administrative Law Judge has suggested action to correct the defects cited in Conclusion 4 as noted at Finding No. 76.

7. Due to Conclusion 4, this Report has been submitted to the Chief Administrative Law Judge for his approval pursuant to Minn. Stat. § 14.15, subd. 3.

8. Any Findings which might properly be termed Conclusions and any Conclusions which might properly be termed Findings are hereby adopted as such.

9. A Finding or Conclusion of need and reasonableness in regard to any particular rule subsection does not preclude and should not discourage the Department from further modification of the proposed rules based upon an examination of the public comments, provided that no substantial change is made from the proposed rules as originally published, and provided that the rule finally adopted is based upon facts appearing in the record.

Based upon the foregoing Conclusions, the Administrative Law Judge makes the following:

RECOMMENDATION

IT IS HEREBY RECOMMENDED that the proposed rules be adopted except where otherwise noted above.

Dated this 8th day of February, 1999.

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BARBARA L. NEILSON
Administrative Law Judge

Reported: Tape Recorded; No Transcript Prepared.

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[1] Minn. Stat. §§ 14.131 through 14.20 (1998).

[2] Minn. Stat. § 14.15, subd. 1 (1998).

[3] Minn. Stat. § 14.15, subds. 3-4 (1998).

[4] Minn. R. 1400.2240, subp. 5 (1997).

[5] *See* http://www.health.state.mn.us/divs/fpc/news.html.

[6] Exhibit 9.

[7] SONAR at 14.

[8] SONAR at 2. The Department also cites the 1997 amendments to Minn. Stat. § 144A.4605 that created a new home care provider license category entitled "assisted living home care provider," as having bearing on this rulemaking.[8] Similarly, the Department points out that Minn. Stat. § 144D, governing housing with services, "directly relates to this rulemaking proceeding . . . ." *Id*. at 3, 6.

[9] SONAR at 14-22.

[10] SONAR at 14-16.

[11] SONAR at 16.

[12] SONAR at 17.

[13] SONAR at 19.

[14] SONAR at 19-21.

[15] SONAR at 21.

[16] Laws of Minnesota 1997, Chap. 303, Sec. 1 (codified as Minn. Stat. § 14.002).

[17] SONAR at 96.

[18] SONAR at 96-97.

[19] Minn. Stat. § 14.14, subd. 2 (1998), and Minn. Rule 1400.2100 (1997).

[20] *Manufactured Housing Institute v. Pettersen*, 347 N.W.2d 238, 244 (Minn. 1984); *Mammenga v. Department of Human Services*, 442 N.W.2d 786 (Minn. 1989).

[21] *In re Hanson*, 275 N.W.2d 790 (Minn. 1978); *Hurley v. Chaffee*, 231 Minn. 362, 367, 43 N.W.2d 281, 284 (1950).

[22] *Greenhill v. Bailey*, 519 F.2d 5, 10 (8th Cir. 1975).

[23] *Mammenga v. Department of Human Services*, 442 N.W.2d 786, 789-90 (Minn. 1989); *Broen Memorial Home v. Minnesota Department of Human Services*, 364 N.W.2d 436, 444 (Minn. Ct. App. 1985).

[24] *Manufactured Housing Institute*, 347 N.W.2d at 244.

[25] *Federal Security Administrator v. Quaker Oats Company*, 318 U.S. 2, 233 (1943).

[26] Minn. Rule 1400.2100 (1997).

[27] Minn. Stat. § 14.15, subd. 3 (1998).

[28] Minn. Stat. § 14.05, subd. 2 (1998).

[29] Public Exhibit 2 at 2.

[30] Public Exhibit 1 at 3.

[31] Department's Dec. 31, 1998, Comment at 1; Department's Jan. 8, 1999, Comment at 1-2.

[32] *Id*.

[33] Public Exhibit 2 at 2.

[34] Public Exhibit 1 at 4.

[35] Exhibit 10.

[36] Department's Dec. 31, 1998, Comment at 5.

[37] *Id*.

[38] *Id.*

[39] Exhibit 10.

[40] Department's Dec. 31, 1998, Comment at 6.

[41] Public Exhibit 1 at 4.

[42] Department's Dec. 31, 1998, Comment at 6.

[43] Exhibit 10.

[44] In the rules as finally proposed, this item has been moved to item H.

[45] In the rules as finally proposed, this item has been moved to item G.

[46] Public Exhibit 1at 6.

[47] Department's Dec. 31, 1998, Comment at 9-10.

[48] Exhibit 10.

[49] Public Exhibit 4 at 3.

[50] Department's Jan.8, 1999, Submission at 4.

[51] Subpart 3, items 8-12.

[52] Exhibit 10.

[53] This term means "as needed."

[54] Exhibit 10.

[55] *Id*. at 4.

[56] Public Exhibit 4.

[57] Department's Dec. 31, 1998, Comment at 18.

[58] *Id.*

[59] *Id*.

[60] Board's Jan. 8, 1999, Comment at 10. The Board also noted that Adult Foster Care settings in which medications are administered will be governed by these rules.

[61] Department's Jan. 8, 1999, Comment at 8.

[62] *Id.* at 11.

[63] *Id.* at 11-12.

[64] Minn. Stat. § 148.171-148.285 (1998). Under the Nurse Practice Act, a nurse's failure to adequately monitor those working at the nurse's direction or the delegation of a nursing function where the delegation could reasonably be expected to result in unsafe or ineffective patient care constitutes grounds for disciplinary action. *See* Minn. Stat. § 148.261, subd. 1(5) and (7).

[65] Minn. R. 6321.0100-6321.0200 (1997).

[66] Minn. Stat. § 144A.45, subd. 1(a) (1998).

[67] Public Exhibit 4.

[68] Public Exhibit 2 at 8.

[69] Exhibit 10.

[70] *See* Minn. Stat. § 144A.4605, subd. 2(f) (1998).

[71] Department's Jan. 8, 1999, Comment at 14.

[72] *Id*.

[73] Minn. Stat. § 14.05, subd. 2 (1998).

[74] Minn. Stat. § 14.05, subd. 2(c)(1)-(3) (1998).